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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,919	10/04/2004	Alain Badore	SSL0082 US PCT	2191
5487	7590	07/10/2007		
ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER RAHMANI, NILOOFAR	
			ART UNIT 1625	PAPER NUMBER
			NOTIFICATION DATE 07/10/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com  
andrea.ryan@sanofi-aventis.com

# Office Action Summary

Application No.

10/509,919

Applicant(s)

BADORC ET AL.

Examiner

Niloofar Rahmani

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 1-5,13-30.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 13-30 is/are pending in the application.
- 4a) Of the above claim(s) 15-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1-5, and 13-30 are pending. Claims 6-12 are cancelled.

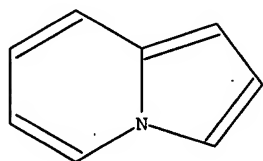
Applicant's election with traverse of group I in the reply filed on 05/23/2007 is acknowledged. The applicant's traverse is on the ground as followed:

1. The relationship among the subject matter defined by the amended claims is such that it involves one or more of the same or corresponding special technical features that make a contribution over the prior art.

2. Compounds defined by the amended claims and utilized in the claimed methods have a common structural core that occupies a large portion of the compounds, constitutes a structurally distinctive portion of the molecules, and makes a contribution over the prior art.

Applicant's argument is not persuasive for the following reasons:

1. The common core is



, because it is the only thing that does not change between group I-IV. Zhang et al. show the same special technical feature (page 51), which a common core is known. Therefore, it is not applicant's contribution to the art.

2. Further, the common structure core is not distinctive portion of the molecule because Zhang et al. taught it.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-5, and 13-14 in part of compounds of formula (I), wherein A being -CO- are examined. Claims 15-30 and 1-5, 13-14 remaining subject matter being drawn to the non-elected invention are withdrawn per 37 CFR 1.142(b).

**2. Priority**

This application is filed on 10/04/2004, which is a 371 of PCT/FR03/01030, filed on 04/02/2003, which claims the priority of FRANCE 0204220, filed on 04/04/2002.

The claimed benefit of priority date is denied. There is no certified translation of the priority document. Therefore, the filing date of the instant date is 04/02/2003.

**3. Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-14 are rejected because the claims are self-conflicting. Pharmaceutical compositions by definition must be effective yet non-toxic. Claims 13-14 are pharmaceutical compositions without dosage limitation i.e. included both ineffective and toxic amount. It is recommended that "therapeutically effective amount" be incorporated in the claims.

#### **4. Claim Rejections - Obvious Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 13-14 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-5, 7-10 of US 2006/0199962. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

##### Determination of the scope and content of the prior art (MPEP §2141.01)

Alcouffe et al. of US 2006/0199962 claimed identical compounds in claims 1-5, 7-10 as the instant claims 1-5, 13-14.

##### Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

##### Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

The issued claims 1-5,7-10 are therefore fully embraced by the instant claims 1-5,13-14 of US 2006/0199962.

**5. Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are provisionally rejected under 35 U.S.C. 102(a) as being anticipated by Bora et al., Organic Letters, 2003, Vol. 5, pages 435-438. Bora et al. disclosed the instant claimed compounds, on page 436, scheme 1, compound 4a, and on page 437, Table 2, compounds 1-3, and on page 438, scheme 3, compound 4a, where in the instant claims R<sub>1</sub> being carboxyl radical. Therefore, the instant claim is anticipated by Bora et al.

**6. Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kakehi et al., Bulletin of the chemical society of Japan, 1996, Vol. 69, pages

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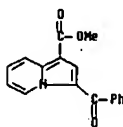
1769-1776. Kakehi et al. disclosed the instant claimed compounds on page 1771, compound 12b, wherein the instant claims  $R_1$  being carboxyl radical.

Therefore, the instant claim is anticipated by Kakehi et al.

7. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Wei et al., Journal of the chemical society, Perkin Transactions 1: Organic and Bio-organic chemistry, 1993, Vol. 20, pages 2487-9. Wei et al. disclosed the instant claimed compounds, which from the STN search are

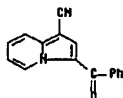
**RN** 17281-79-7

**CN** 1-Indolizinecarboxylic acid, 3-benzoyl-, methyl ester



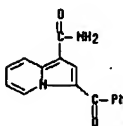
**RN** 25627-81-0

**CN** 1-Indolizinecarbonitrile, 3-benzoyl



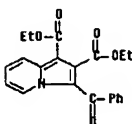
**RN** 25627-86-5

**CN** 1-Indolizinecarboxamide, 3-benzoyl



**RN** 154224-58-5

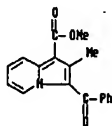
**CN** 1,2-Indolizinedicarboxylic acid, 3-benzoyl-, diethyl ester



**RN** 154224-59-6

**CN** 1-Indolizinecarboxylic acid, 3-benzoyl-2-methyl-, methyl ester

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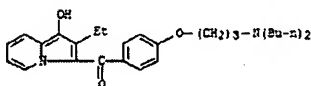
. Therefore,  
the instant claim is anticipated by Wei et al.

8. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamura et al., Journal of the chemical society, Perkin Transactions 1: Organic and Bio-organic chemistry, 1973, Vol. 19, pages 2091-5. Tamura et al. disclosed the instant claimed compound on page 2092, compound (VI), wherein the instant claims  $R_1$  being carboxyl radical. Therefore, the instant claim is anticipated by Tamura et al.

9. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Overzet et al., Journal of pharmaceutical and biomedical analysis, 1984, Vol. 2, pages 3-17. Overzet et al. disclosed the instant claimed compound, which from the STN search is

**RN** 94419-24-6

**CN** Methanone, [4-[3-(dibutylamino)propoxy]phenyl](2-ethyl-1-hydroxy-3-IndolizinyI)



wherein the instant claims  $R_1$  being hydroxyl and  $R_2$  being carboxyl radicals .

Therefore, the instant claim is anticipated by Overzet et al.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is



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571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

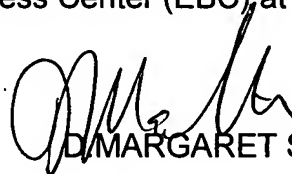
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

06/29/2007

NIL



MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625